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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,131	12/31/2003	Paul F. Chouinard	BSI-463US2	9781

23122 7590 11/19/2007
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EXAMINER	
WOO, JULIAN W	
ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,131	CHOUINARD ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23-28* is/are allowed.

6)☒ Claim(s) *1-22 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on August 22, 2007 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 6,685,738 is undergoing review.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "[E]ndoluminal device" and "the device" lack antecedent bases.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-16, 22, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Parker (5,769,830). Parker discloses, at least in figures 1 and 3 and in col. 4, lines 49-59 and col. 5 line 40 to col. 6, line 26; an endoluminal implant (44) or device and a method for treating a human being, where the

implant or device and method include a plurality of continuous filaments braided together (26), at least one filament comprising at least one first region having a first cross-sectional area or round first cross-section and at least one second region having second cross-sectional area (at 40) or a round (semi-circular) second cross section, where the first cross-sectional area (at proximal portion of 40) or first cross-section is larger than the second cross-sectional area (at distal portion of 40) or second cross-section, where the at least one filament comprises a step-change between the first region and the second region (see the change in cross-section at fig. 3), where the all the plurality of continuous filaments comprise a step-change between each first region and each second region, where at least one filament comprises a tapered filament, where the all of the plurality of continuous filaments comprise tapered filaments (at 40), where the endoluminal device comprises an end having atraumatic end windings (i.e., curved end surfaces), where the at least one filament comprises a circular cross-section (at proximal portion of 44), where the at least one filament comprises a non-round cross-section (at distal portion of 40), where the endoluminal implant tapers from a first end having a first diameter to a second end having a second diameter smaller than the first diameter, where at least one filament comprises a third region having a cross-sectional area intermediate the first and second cross-sectional areas, where a first end of the endoluminal implant has a first diameter and a second end of the endoluminal implant has a second diameter smaller than the first diameter, where the endoluminal implant includes a first region of the filament having the first cross-sectional area at the first end of the

endoluminal implant and a second region of the filament having the second cross-sectional area at the second end of the endoluminal implant, where the endoluminal implant includes an intermediate portion (middle of 40) having a third diameter intermediate the first and second diameters, and the intermediate portion includes a third region of the at least one filament having a third cross-sectional area intermediate the first and second cross-sectional areas, where the endoluminal implant includes first and second portions, where the second portion is more flexible than the first portion (if the second portion includes element 12) and comprises the second region of the at least one filament having the second cross-sectional having the second cross-sectional area, and where the filaments comprise stainless steel wire.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parker (5,769,830) in view of Truckai (5,019,057). Parker discloses the invention substantially as claimed, but does not disclose filaments comprising polymeric material. Truckai teaches, at least in col. 2, lines 38-51; a catheter including filaments of polymeric material (e.g, nylon or polyester). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Truckai, to modify the device of Parker, so that it includes polymeric filaments. Such filaments would improve the pushability (i.e., stiffness) of the catheter at portions of the catheter where they are applied.

8. Claims 18-20 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker (5,769,830). Parker discloses the invention substantially as claimed, but does not specifically disclose the that the endoluminal implant or device includes a radially compressed configuration and a radially expanded configuration, where the expansion is of the mode as claimed, and where the endoluminal implant comprises a filament braiding ratio as claimed. However, Parker discloses, in col. 1, lines 16-18, 30-35, and 60-63; that the endoluminal implant device may include a radially expandable balloon catheter that expands by balloon expansion. It would have obvious to one having ordinary skill in the art at the time the invention was made, to include a balloon catheter with the endoluminal device of Parker. Such a component would allow the device of Parker to further treat blood vessels (by angioplasty) through which the device is designed to traverse. Moreover, it would have been

obvious to one having ordinary skill in the art at the time the invention was made to braid the filaments in the ratios as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ratios (according to the desired stiffness) involves only routine skill in the art.

9. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parker (5,769,830) in view of Wiktor (4,886,062). Parker discloses the invention substantially as claimed. Parker discloses an implant or a guiding catheter applicable with a balloon, but Parker does not disclose that the implant includes a stent. Wiktor teaches, at least in figure 3 and 4 and in col. 3, line 39 to col. 4, line 45; a guiding catheter (9) including a balloon (5) and a stent (1). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wiktor, to include a stent (and balloon) with implant of Parker. Such a modification would allow Parker's implant to perform angioplasty to recanalize the lumen of a blood vessel and to deploy a stent within the lumen to prevent possible reclosure and restenosis.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 5, 6, 9, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 10, and 22 of U.S. Patent No. 6,325,822. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim an endoluminal device and a method for treating a human being, where the device and method comprise a plurality of continuous filaments braided together, at least one filament comprising at least one first region having a first cross-sectional area and at least one second region having second cross-sectional area, where the first cross-sectional area is larger than the second cross-sectional area, where the continuous filaments comprise tapered filaments, where the device comprises atraumatic end windings, and where the device tapers from a first end having a first diameter to a second end having a second diameter.

12. Claims 21 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 19 of U.S. Patent No. 6,685,738. Although the conflicting claims are not identical, they are not

patentably distinct from each other because they claim, inter alia, an endoluminal device and a method for treating a human being, where the device includes a body and a plurality of legs, where each leg comprises continuous filaments braided together and at least a portion of the body comprises continuous filaments braided together and includes filaments from each of the legs; and where the device and method comprise continuous filaments braided together, where at least one filament comprises at least one first region having a first cross-sectional area and at least one second region having second cross-sectional area, where the first cross-sectional area is larger than the second cross-sectional area.

Allowable Subject Matter

13. Claims 23-28 are allowed.

14. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a process for constructing a braided, branched stent having a body and a plurality of legs, where each leg comprises the braiding of a discrete plurality of continuous filaments, where a first body portion of the body is formed by the braiding of at least one filament from each of the plurality of continuous filaments of the legs, and where the braiding comprises braiding at least one tapered filament , where the filament includes a first region having a first, relatively larger cross-sectional area and at least one second region has a second, relatively smaller cross-sectional area.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Amendment

15. Applicant's arguments filed on August 22, 2007 have been fully considered but they are not persuasive. With respect to arguments regarding the rejections based on the Parker reference: The Applicant has asserted that Parker "fails to disclose or suggest that his device is an implant." On the contrary, "implant" has been given its broadest reasonable interpretation with a definition that includes "something inserted during surgery" (ENCARTA World English Dictionary). The definition gives no weight to the length of time that the "something" remains in a body. That is, Parker indeed discloses an implant, albeit, an implant that may be temporary or left in a body lumen for a relatively short period of time. Moreover, catheters in the art have been known to be remain in the body for long terms; e.g., urinary catheters and Hickman lines, and these catheters may be considered implants as well.

With respect to arguments regarding the double patenting rejections: The terminal disclaimer filed on August 22, 2007 is being reviewed as of the date of this Office action. The double rejections remain standing until the terminal disclaimer has been approved.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo
Primary Examiner

November 14, 2007